REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 2-4, 7-8, 10-12, and 16 are pending. Claims 2-4, 7-8 and 10-12 have been amended to recite that the strain of bacteria is "live". Support for this change may be found in the present specification at page 5, first full paragraph. Claim 10 has been amended to recite that the composition comprises the strain and an "oral care drug". Support for this change may be found in the present specification at page 14, lines 1-3. New claims 16 has been added. Support for new claim 16 may be found in the specification on page 8, third full paragraph. Claims 1, 5, 6, 9, and 13-15 have been canceled without prejudice and may be the subject of a future application.

Claims 1, 5, 9, and 10 were rejected under 35 USC 112, second paragraph for allegedly being indefinite. Applicants believe that the present amendment overcomes the rejections.

Applicants respectfully submit that the phrase "normalizing intraoral microflora" is definite to one skilled in the art. The term "intraoral" refers to the area of the mouth. The term "microflora" refers to naturally occurring microorganisms that inhabit areas such as the mouth and intestines. Pathological microorganisms may sometimes abnormally proliferate and degrade the state of these naturally occurring microorganisms. The phrase "normalize microflora" is often used in the field of microbiology (e.g., U.S. Patent No. 5,622,927, 5,958,461, 6,132,710, and 6,699,504) and refers to restoring a "microflora" to its natural state. One skilled in the art would have known that the phrase "normalizing intraoral microflora" refers to restoring the

natural state of microorganisms that exist in the area of the mouth. Thus, applicants believe that the phrase is definite to one skilled in the art.

Nevertheless, applicants note that claims 1 and 5 have been canceled without prejudice and respectfully ask that the rejection be withdrawn.

Claim 9 has been canceled without prejudice.

As noted above, claim 10 has been amended so that the phrase "active ingredient" is no longer recited.

In view of the above, applicants ask that the rejections be withdrawn.

Claims 5-15 were rejected under 35 USC 112, first paragraph for allegedly not satisfying the enablement requirement. This rejection is traversed.

Applicants confirm that the strain *Lactobacillus salivarius* TI 2711 (FERM BP-7974) was deposited in accordance with the terms of the Budapest Treaty. Applicants also confirm that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent (with the possible exception of requiring the request for the deposit to be in the format specified in 37 CFR 1.808(b)).

In view of the above, applicants ask that the rejection be withdrawn.

Claims 6 and 9 were rejected under 35 USC 101 for allegedly not reciting statutory subject matter. These rejections are traversed.

In accordance with the Examiner's suggestion, claim 6 now recites a "purified" culture. Applicants thank the Examiner for the suggestion as how to overcome the rejection.

Claim 9 has been canceled without prejudice and applicants ask that the rejection be withdrawn.

Claims 1-10 and 13-15 were rejected under 35 USC 102 (b) as allegedly being anticipated by KAWAI et al (U.S. Patent No. 4,746,512). This rejection is traversed.

Claims 2-4, 7-8, and 10-12 recite a live bacterium preparation that comprises live cells of the *Lactobacillus salivarius* TI 2711 strain. Claim 16 is directed to an isolated strain of *Lactobacillus salivarius* TI 2711 strain (FERM BP-7974). The claimed live bacterium preparation and claimed isolated strain may be used in probiotic compositions.

According to the joint expert meeting of United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO), "probiotics" are defined to be "live microorganisms which when administered in adequate amounts confer a health benefit on the host." It is necessary that the live microorganisms can survive at a target site to exhibit their desired effects.

The bacterial cells of the present invention can survive at a target site to exhibit their desired effects and metabolize substances in the oral cavity even after ingestion to produce and secrete various substances. In other words, the cells of the specific *Lactobacillus* bacterium of the present invention continue to survive at the administration site to exhibit the desired effect. In addition, the cells contained in the live bacterium preparation of the present invention contain or produce and secrete proteins and other physiologically active substances in an active state, which are very likely to be inactivated under sterilization conditions.

In this regard, the Examiner's attention is respectfully directed to Test Example 3. Test Example 3 shows that the results of a clinical test that studies the superior effectiveness of the claimed live bacterium preparation and isolated strain. The test results are discussed on page 27 of the specification and shown in Figures

3-9. The test results show that the claimed live bacterium preparation and isolated strain are effective in treating halitosis, not harmful to the human intraoral microflora, and helpful in maintaining a normal intraoral pH. The safety of the claimed live bacterium preparation and isolated strain were also confirmed by the clinical test.

KAWAI relates to an anti-cariogenic or anti-periodontitic agent containing, as an active component, bacterial cell components and/or water-soluble extracts (i.e., not a whole, viable cell) of a microorganism belonging to the genus Streptococcus or the genus Lactobacillus. The active ingredient of KAWAI consists of dead cell components obtained by subjecting cells to a sterilization treatment such as sterilized hot water extraction or thermal sterilization (e.g., see col. 5). Thus, the active ingredient of KAWAI is distinct from the active ingredient of the claimed live bacterium.

As a result, it is believed that KAWAI fails to anticipate the claimed live bacterium preparation.

Furthermore, applicants respectfully submit that it can not be said that the strains disclosed by KAWAI "inherently" anticipate the claimed strain. As noted above, the inventors of the present application have discovered for the first time a bacterial cell strain with properties suitable as a probiotic. The properties of a bacterial strain simply can not be predicted from the properties of dead cell components. In this regard, applicants respectfully submit that one skilled in the art could not expect or predict that the bacterial strains of KAWAI would have the same properties of the claimed live bacterium preparation of claimed isolated bacteria. Indeed, the Official Action fails to provide any evidence in support of this position.

MPEP § 2112 states that to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). As the Official Action fails to provide any evidence in support of the allegation and in view of the evidence set forth in the present specification, applicants respectfully submit that KAWAI also fails to anticipate the claimed strain.

For the reasons described above, the present invention is neither anticipated nor obvious over Kawai et al.

Claims 10-12 were rejected under 35 USC 103(a) as allegedly being obvious over KAWAI in view of KLUEPPEL et al (U.S. Patent No. 4,726,943). This rejection is traversed.

Applicants respectfully submit that KLEUEPPEL fails to remedy the deficiencies of KAWAI for reference purposes. KLUEPPEL teaches the use polyols (col. 2, lines 14-19). KLUEPPEL does not disclose of suggest the claimed live bacterium preparation or claimed isolated strain of bacteria.

As for the combination of the bacterial strain of the present invention and another oral care drug, applicants respectfully submit that a synergistic effect of the combination, especially the combination with erythritol, is demonstrated by the results of Example 5 of the present specification. This is particularly the case when taking into the live cell counts of *S. mutans*, which exceeds the additive effect obtained with the independent use of the bacterial strain and oral care drugs. Such

a synergistic effect cannot be expected at all from a combination of KAWAI and KLUEPPEL, which describes only the activity of sugar alcohols. Therefore, the present invention is not obvious over KAWAI and KLUEPPEL.

Moreover, it cannot be said that the recited bacterial strain (i.e., *Lactobacillus salivarius* TI 2711 (FERM BP-7974)) and erythritol were known as being useful for the same purpose. Indeed, as note above, *Lactobacillus salivarius* TI 2711 (FERM BP-7974) is a novel strain of a bacteria. Thus, applicants respectfully submit that the reliance upon *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) is inappropriate and respectfully ask that the rejection be withdrawn.

Accordingly, applicants ask that the obviousness rejection be withdrawn.

In view of the above, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Respectfully Submitted,
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